

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number	09890335
Filing Date	2002-04-08
First Named Inventor	Cevc
Art Unit	1645
Examiner Name	B.J. Gangle
Attorney Docket Number	

**U.S. PATENTS**

Examiner Initial*	Cite No	Patent Number	Kind Code <sup>1</sup>	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear
	1	6448296	A1	2002-09-10	Yasueda et al.	
	2	6451339	A1	2002-09-17	Patel et al.	
	3	6562370	A1	2003-05-13	Luo et al.	
	4	6582724	A1	2003-06-24	Hsu et al.	
	5	6586000	A1	2003-07-01	Luo et al.	
	6	6645520	A1	2003-11-11	Hsu et al.	
	7	6645529	A1	2003-11-11	Gergely et al.	
	8	6726598		2004-04-27	Jarvis et al.	

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number		09890335
Filing Date		2002-04-08
First Named Inventor	Cevc	
Art Unit	1645	
Examiner Name	B.J. Gangle	
Attorney Docket Number		

9	6835392	A1	2004-12-28	Hsu et al.	
10	RE33273		1990-07-24	Speaker	
11					

If you wish to add additional U.S. Patent citation information please click the Add button.

**U.S. PATENT APPLICATION PUBLICATIONS**

Examiner Initial*	Cite No	Publication Number	Kind Code <sup>1</sup>	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear
	1					

If you wish to add additional U.S. Published Application citation information please click the Add button.

**FOREIGN PATENT DOCUMENTS**

Examiner Initial*	Cite No	Foreign Document Number <sup>3</sup>	Country Code <sup>2</sup>	Kind Code <sup>4</sup>	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear	T <sup>5</sup>
	1	93/19737	WO		1993-10-14	Kabi Pharmacia AB		<input type="checkbox"/>
	2	05/063213	WO		2005-07-14	Biodelivery Sciences International, Inc.		<input type="checkbox"/>
	3	95/09831	WO		1995-04-13	Nicox Ltd. et al.		<input type="checkbox"/>

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number		09890335
Filing Date		2002-04-08
First Named Inventor	Cevc	
Art Unit	1645	
Examiner Name	B.J. Gangle	
Attorney Docket Number		

4	06/050926	WO		2006-05-18	IDEA AG		<input type="checkbox"/>
5	02/32398	WO		2002-04-25	Massachusetts Institute of Technology		<input type="checkbox"/>
6	98/33483	WO		1998-08-06	Depotech Corporation		<input type="checkbox"/>
7	93/19736	WO		1993-10-14	Kabi Pharmacia AB		<input type="checkbox"/>
8	01/01962	WO		2001-01-11	IDEA Innovative GmbH		<input type="checkbox"/>
9	90/11065	WO		1990-10-04	Theratec, Inc.		<input type="checkbox"/>
10	00/13684	WO		2000-03-16	Loma Linda University Medical Center		<input type="checkbox"/>
11	94/26257	WO		1994-11-24	LTS Lohmann Therapie-Systeme GmbH & Co.		<input checked="" type="checkbox"/>
12	00/12060	WO		2000-03-09	Cevc		<input type="checkbox"/>
13	92/05771	WO		1992-04-16	Kabi Pharmacia		<input type="checkbox"/>
14	99/22703	WO		1999-05-14	Lurident Ltd.		<input type="checkbox"/>

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number	09890335
Filing Date	2002-04-08
First Named Inventor	Cevc
Art Unit	1645
Examiner Name	B.J. Gangle
Attorney Docket Number	

If you wish to add additional Foreign Patent Document citation information please click the Add button

**NON-PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>6</sup>
	1	Karzel and R.K. Liedtke, "Mechanism Transkutaner Resorption." on Grundlagen/Basics, pp. 1487-1491	<input checked="" type="checkbox"/>
	2	Katoulis et al., "Efficacy of a new needleless insulin delivery system monitoring of blood glucose fluctuations and free insulin levels," on International J. of Artificial Organs 12(5):333-338 (1989)	<input type="checkbox"/>
	3	Klibanov, et al., "Activity of amphipathic poly(ethylene glycol) 5000 to prolong the circulation time of liposomes depends on the liposome size and is unfavorable for immunoliposome binding to target," BBA 1062:142-148 (1991)	<input type="checkbox"/>
	4	Knepp et al., "Controlled drug release from a novel liposomal delivery system II. Transdermal delivery characteristics," J. Contr. Release 12(1):25-30 (Mar. 1990) Amsterdam, NL	<input type="checkbox"/>
	5	Lasch, J. et al., "Interactions of external lipids (lipid vesicles) with the skin" J. Liposome Research 5(3):543-569 (1995)	<input type="checkbox"/>
	6	Lehmann, J. et al., "Analgesic and anti-inflammatory efficacy of IDEA-070 in UVB-induced sunburn." J. Eur. Acad. Dermatol. Venereol. 18(S2):267-268 (Oct. 2004)	<input type="checkbox"/>
	7	Lichtenberg, D. et al., "Solubilization of phospholipids by detergents: structural and kinetic aspects" BBA 737:285-304 (1983)	<input type="checkbox"/>
	8	Lobbecke, et al., "Effects of short-chain alcohols on the phase behavior and interdigitation of phosphatidylcholine bilayer membranes" BBA 1237:59-69 (1995)	<input type="checkbox"/>
	9	Mayer, L.D. et al., "Vesicles of variable sizes produced by a rapid extrusion procedure," BBA 858:161-168 (1986)	<input type="checkbox"/>

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number		09890335
Filing Date		2002-04-08
First Named Inventor	Cevc	
Art Unit	1645	
Examiner Name	B.J. Gangle	
Attorney Docket Number		

10	Merck Index: 10th Edition, 1983. Pages 779-780.	<input type="checkbox"/>
11	Mezei, "Liposomes as a skin drug delivery system," 1985 Elsevier Science Publishers B.V. (Biomedical Division) pp.345-358	<input type="checkbox"/>
12	Ogiso, Taro et al., "Membrane-controlled transdermal therapeutic system containing clonazepam and anticonvulsant activity after its application," Chem. Pharm. Bull. 37(2):446-449 (1989)	<input type="checkbox"/>
13	Patel, H.M. et al., "Oral administration of insulin by encapsulation within liposomes," FEBS Letters 62(1):60-63 (Feb. 1976)	<input type="checkbox"/>
14	Patel, H.M., "Liposomes as a controlled-release system," Biomedical Society Transactions 609th Meeting, Leeds, pp.513-516.	<input type="checkbox"/>
15	Peters, et al., "Pharmacodynamics of a liposomal preparation for local anaesthesia," Arzneimittel-Forsch/Drug Res. 45(II), Nr12 (1995), pages 1253-56	<input type="checkbox"/>
16	Planas, et al., "Noninvasive percutaneous induction of topical analgesia by a new type of drug carrier, and prolongation of local pain insensitivity by anesthetic liposomes," Anesth. Analg. 75:615-621 (1992)	<input type="checkbox"/>
17	Price, C.E., "A review of the factors influencing the penetration of pesticides through plant leaves," on I.C.I. Ltd., Plant Protection Division, Jealott's Hill Research Station, Bracknell, Berkshire RG12 6EY, U.K., pp. 237-252	<input type="checkbox"/>
18	Product Information: "Polysorbate 80 VG" (2004)	<input type="checkbox"/>
19	Product Information: "Tween 80 Pure" (2004)	<input type="checkbox"/>
20	Prof. Dr. K-U Benner, Der Körper des Menschen, "The human body" Weltbild GmbH Augsburg Chapter 4 page 49 (1995)	<input checked="" type="checkbox"/>

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
(Not for submission under 37 CFR 1.99)

Application Number		09890335
Filing Date		2002-04-08
First Named Inventor	Cevc	
Art Unit	1645	
Examiner Name	B.J. Gangle	
Attorney Docket Number		

21	Ranade V., "Drug delivery systems. 6. Transdermal drug delivery," J. Clin. Pharmacol. 31:401-418 (1991)	<input type="checkbox"/>
22	Roeding, J. "Liposomes and niosomes in pharmacy and cosmetics state of art prospects, techniques of visualizing vesicular systems, interaction of liposomes with the skin" Training course no. 105 from May 14-16, 1990, Maritim Hotel Nurnberg, Frauentorgraben 11, 8500, Nurnberg.	<input type="checkbox"/>
23	Schramlova, J. et al., "The effect of an antiphlogistic incorporated in liposomes on experimentally induced inflammation," Folia Biologica (Praha) 43:195-199 (1997)	<input type="checkbox"/>
24	Schreier, H. "Liposomes - A novel drug carrier. I. Phospholipids; production and characterization of liposomes; II. Destiny of liposomes in vivo; use in therapy." Pharmazie in unserer Zeit, No. 4 (1982)	<input type="checkbox"/>
25	SERVA Feinbiochemica, Katalog, pages 201-202 (1986/1987)	<input type="checkbox"/>
26	Siddiqui, O. et al., "Nonparenteral administration of peptide and protein drugs," CRC Critical Review in Therapeutic Drug Carrier Systems, Vol. 3, Issue 3 pg. 195-208	<input type="checkbox"/>
27	Stoye, I. et al., "Transformation of a liposomal dispersion containing ibuprofen lysinate and phospholipids into mixed micelles - physico-chemical characterization and influence on drug permeation through excised human stratum corneum," Eur. J. Pharmaceuticals and Biopharmaceuticals 46:191-200 (1998)	<input type="checkbox"/>
28	Swenson, E. Scott and William J. Curatolo, "Intestinal permeability enhancement for proteins, peptides and other polar drugs: mechanisms and potential toxicity" Advanced Drug Delivery Reviews, 8:39-92 (1992)	<input type="checkbox"/>
29	Trotta, M. et al., "Deformable liposomes for dermal administration of methotrexate," International J. of Pharmaceutics (Kidlington) 270(1-2) 11 Feb 2004, pages 119-125	<input type="checkbox"/>
30	Trotta, M. et al., "Elastic liposomes for skin delivery of dipotassium glycyrrhizinate," International J. of Pharmaceutics (Kidlington) 241(2) 25 Jul 2002, pages 319-327	<input type="checkbox"/>
31	Valenta, C. et al. "Evaluation of novel soya-lecithin formulations for dermal use containing ketoprofen as a model drug," J. Contr. Release 63:165-173 (2000)	<input type="checkbox"/>

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number		09890335
Filing Date		2002-04-08
First Named Inventor	Cevc	
Art Unit	1645	
Examiner Name	B.J. Gangle	
Attorney Docket Number		

32	Vinggaard, A.M., et al., "Didecanoyl phosphatidylcholine is a superior substrate for assaying mammalian phospholipase D." Biochem. J. 319:861-864 (1996)	<input type="checkbox"/>
33	Vinson, P. et al., "Vesicle-micelle transition of phosphatidylcholine bilayers and octylglucoside elucidated by cryo-transmission electron microscopy," Biophys. J., Biophysical Society Vol. 56, October 1989 pages 669-681.	<input type="checkbox"/>
34	Vyas et al., "Liposomally encapsulated diclofenac for sonophoresis induced systemic delivery," J. Microencapsulation, 1995, 12(2):149-154.	<input type="checkbox"/>
35	Wearley LL, "Recent progress in protein and peptide delivery by noninvasive routes." Crit. Rev. Ther. Drug Carrier Syst. 8:331-94 (1991)	<input type="checkbox"/>
36	Wess, L., "All in the Family." Biocentury, the Bernstein Report on Biobusiness, 12(22):A11-A12 17 May 2004 (2004-05-17)	<input type="checkbox"/>
37	Yuan, et al., "Cationic liposome and gene transfer," Progress in Physiological Science, 28(2): 163-165 (1997) (English translation only)	<input checked="" type="checkbox"/>
38	Jackson, M.L. et al., "Solubilization of phosphatidylcholine bilayers by octyl glucoside" Biochemistry 21:4576-4582 (1982)	<input type="checkbox"/>
39	English language abstract of EP 0 298 280 A from Derwent	<input type="checkbox"/>
40	English language abstract of EP 0 102 324 from Derwent	<input type="checkbox"/>
41	Pierson et al., "Synthesis and biological evaluation of potent, selective, hexapeptide CCK-A agonist anorectic agents" J. Med. Chem. 40:4302-07 (1997)	<input type="checkbox"/>
42	Lee et al., "Intranasal bioavailability of insulin powder formulations: Effect of permeation enhancer-to-protein ratio" J. Pharm. Sci. 80(8):725-29 (1991)	<input type="checkbox"/>

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT****( Not for submission under 37 CFR 1.99)**

Application Number	09890335
Filing Date	2002-04-08
First Named Inventor	Cevc
Art Unit	1645
Examiner Name	B.J. Gangle
Attorney Docket Number	

43	Shao et al., "Cyclodextrins as nasal absorption promoters of insulin: Mechanistic evaluations" Pharm. Res. 9 (9):1157-63 (1992)	<input type="checkbox"/>
44	Iijim et al., "Chitosan as a novel nasal delivery system for peptide drugs" Pharm. Res. 11(8):1186-89 (1994)	<input type="checkbox"/>
45	Lowell et al., "Proteosomes, emulsomes, and cholera toxin B improve nasal immunogenicity of human immunodeficiency virus gp160 in mice: Induction of serum, intestinal, vaginal, and lung IgA and IgG" J. Infect. Dis. 175:292-301 (1997)	<input type="checkbox"/>
46	Schreier et al., "Liposomen - ein neuartiger Arzneistoffträger II. Schicksal von Liposomen in vivo: Einsatz in der Therapie", Pharmazie in unserer Zeit No. 4 (1982), pages 103-108	<input type="checkbox"/>

If you wish to add additional non-patent literature document citation information please click the Add button

**EXAMINER SIGNATURE**

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> See Kind Codes of USPTO Patent Documents at [www.USPTO.GOV](http://www.USPTO.GOV) or MPEP 901.04. <sup>2</sup> Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>3</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>4</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>5</sup> Applicant is to place a check mark here if English language translation is attached.